



In the United States Patent & Trademark Office

In re Application of: *Adrian Clausell, Jirong Gu and M. Parameswara Reddy*

Serial No.: Unknown

Filed: Unknown

Title: **Methods and Reagents for Improved Cell-Based Assays**

RECEIVED

Examiner:

APR 12 2002

Art Unit:

TECH CENTER 1600/2900

Atty Dkt. No.: 3501.117

RECEIVED

JAN 31 2002

TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §§ 1.197(b)(1) AND 1.56

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

In accordance with 37 CFR §§ 1.97 and 1.56, Applicant herewith submits the following Information Disclosure Statement. A copy of all cited documents are enclosed herewith.

This Information Disclosure Statement is being submitted within 3 months of the filing date of the present application. Accordingly, no fee is required for its consideration and for the consideration of the cited documents. The cited documents are:

- | | | | |
|-----|--------------------------------|-----|-----------------------------|
| AA1 | 4,557,862 (Mangel, et al.) | AB2 | 5,698,411 (Lucas, et al.) |
| AB1 | 4,640,893 (Mangel, et al.) | AC2 | 5,759,781 (Ward, et al.) |
| AC1 | 4,940,659 (Warrington, et al.) | AD2 | 5,976,822 (Landrum, et al.) |
| AD1 | 5,070,012 (Nolan, et al.) | AE2 | 6,174,673 (Short, et al.) |
| AE1 | 5,238,108 (Velezis, et al.) | AA3 | 6,248,904 (Zhang, et al.) |
| AA2 | 5,310,687 (Bard, et al.) | AB3 | 6,281,021 (Egger, et al.) |
-
- | | |
|-----|---|
| AR1 | Alberts, B. <i>et al.</i> , Molecular Biology of the Cell, 2nd Edition. Garland Publishing, Inc. New York, pg 704. |
| AS1 | Alnemri, <i>et al.</i> , "Human ICE/CED-3 protease nomenclature," <i>Cell</i> , 1996 Oct 18;87(2):171. |
| AT1 | Ashmum RA and Look AT. 1990, "Metalloprotease Activity of CD13/Aminopeptidase N on the Surface of Human Myeloid Cells," <i>Blood</i> 75: 462-469. |

- AR2 Bass, D.A. *et al.* "Flow cytometric studies of oxidative product formation by neutrophils: a graded response to membrane stimulation." *J. Immunol.* 130: 1910-1917.
- AS2 Bode, W. *et al.*, 1989, "Human leukocyte and porcine pancreatic elastase: X-ray crystal structures, mechanism, substrate specificity and mechanism-based inhibitors," *Biochem.* 28: 1951-1963.
- AT2 Coates, P.M. *et al.*, 1975, "A preliminary genetic interpretation of the esterase isozymes of human tissues," *Ann. Hum. Genet. Lond.* 39: 1-20.
- AR3 Crockard, A. *et al.*, 1982, "Cytochemistry of acid hydrolases in chronic B- and T-cell leukemias," *Am. J. Clin. Pathol.* 78:437-444.
- AS3 Darzynkiewicz, Z. *et al.* "Flow cytometry in analysis of cell cycle and apoptosis," *Semin Hematol.* 2001 Apr;38(2):179-93.
- AT3 Duque, R. E., "Flow Cytometric Analysis of Lymphomas and Acute Leukemias", *Annals of the New York Academy of Sciences, Clinical Flow Cytometry*, 677, pp. 309-325 (Mar. 20, 1993).
- AR4 Ferrer-Lopez, P. *et al.*, "Heparin Inhibits Neutrophil-Induced Platelet Activation Via Cathepsin", *J. Lab Clin. Med.* 119(3), 231-239 (1992).
- AS4 Fleischer, B., 1994, "CD26: a surface protease involved in T-cell activation," *Immunol. Today.* 15: 180-184.
- AT4 Gartner, T.K. *et al.*, 1985, "The tetrapeptide analogue of the alpha chain and decapeptide analogue of the gamma chain of fibrinogen bind to different sites on the platelet fibrinogen receptor," *Blood.* 66 Suppl 1: 305a.
- AR5 Hoffmann, T. *et al.* 1993, "Dipeptidyl peptidase IV (CD 26) and aminopeptidase N (CD 13) catalyzed hydrolysis of cytokines and peptides with N-terminal cytokine sequences," *FEBS Letters.* 336: 61-64.
- AS5 Hohn, P.A. *et al.*, 1989, "Genomic organization and chromosomal localization of the human cathepsin G gene," *J. Biol. Chem.* 264: 13412-13419.
- AT5 Jongkind, J.F. *et al.*, 1986, "Detection of acid-b -galactosidase activity in viable human fibroblasts by flow cytometry," *Cytometry* 7:463-466.
- AR6 Kankaanranta, H. *et al.*, 1994, "Effects of non-steroidal anti-inflammatory drugs on polymorphonuclear leukocyte functions in vitro: focus on fenamates," *Naunyn-Schmiedeberg's Arch Pharmacol.* 350:685-691.
- AS6 Kohen, E. *et al.*, 1993, "An in situ study of beta-glucosidase activity in normal and gaucher fibroblasts with fluorogenic probes," *Cell Biochem. and Function.* 11:167-177.

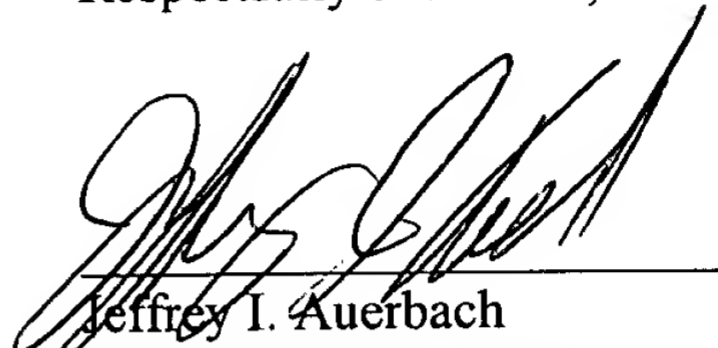
- AT6 Kojima, K. *et al.*, 1979, "A new and highly sensitive fluorescence assay for collagenase-like peptidase activity," *Anal. Biochem.* 100: 43-50.
- AR7 Leytus, S.P. *et al.*, "New class of sensitive and selective fluorogenic substrates for serine proteases," *Biochem. J.* 215:253-260 (1983).
- AS7 Li, C.Y. *et al.*, 1970, "Acid phosphatase isoenzyme in human leukocytes in normal and pathologic conditions," *J. Histochem. Cytochem.* 18:473-481.
- AT7 Look, A.T. *et al.* 1989, "Human myeloid plasma membrane glycoprotein CD13 (gp150) is identical to aminopeptidase N," *J. Clin. Invest.* 83: 1299-1307.
- AR8 McDonald, J.A. *et al.*, 1980, "Degradation of fibronectin by human leukocyte elastase," *J. Biol. Chem.* 255: 8848-8858.
- AS8 Mentlein, R. *et al.*, H. R., "Influence of Pregnancy on Dipeptidyl Peptidase IV Activity (CD26 Leukocyte Differentiation Antigen) of Circulating Lymphocytes", *Eur. J. Clin. Chem. Clin. Biochem.*, 29, 477-480 (1991).
- AT8 Mononen, *et al.*, "Enzymatic diagnosis of aspartylglycosaminuria by fluorometric assay of glycosylasparaginase in serum, plasma, or lymphocytes," *Clin. Chem* 1994 Mar; 40(3):385-8.
- AR9 Park, R.D. *et al.*, "Hypertonic sucrose inhibition of endocytic transport suggests multiple early endocytic compartments," *J. Cell Physiol.* 1988 Jun;135(3):443-450).
- AS9 Rechsteiner, M. "Osmotic lysis of pinosomes," *Methods Enzymol* 1987;149:42-48; Okada, C.Y. *et al.*, "Introduction of macromolecules into cultured mammalian cells by osmotic lysis of pinocytic vesicles," *Cell* 1982 May;29(1):33-41.
- AT9 Riss, T.L. "Apoptosis as a biomarker in chemoprevention trials," *Urology.* 2001 Apr;57(4 Suppl 1):141-2.
- AR10 Rothe *et al.*, "Flow cytometric analysis of protease activities in vital cells," *Biol. Chem. Hoppe Seyler.* 1992 Jul; 373(7): 547-54.
- AS10 Rotman, B. *et al.*, 1963, "Fluorogenic substrates for b-D-galactosidases and phosphatases derived from fluorescein (3,6-dihydroxyfluoran) and its monomethyl ether," *Proc. Nat. Acad. Sci. USA* 50:1-6.
- AT10 Royer, G. *et al.*, "Immobilized Derivatives of Leucine Aminopeptidase and Aminopeptidase M," *J. Biol. Chem.* 248(5), 1807-1812 (1973).
- AR11 Ruiz, P. *et al.*, 1996, "Cytofluorographic evidence that thymocyte dipeptidyl peptidase IV (CD26) activity is altered with stage of ontogeny and apoptotic status," *Cytometry.* 23: 322-329.
- AS11 Sanderink, G.J. *et al.*, 1988, "Human Aminopeptidases: A Review of the Literature. *J. Clin. Chem. Clin. Biochem.* 26: 795-807.

- AT11 Saraste, A. *et al.* "Morphologic and biochemical hallmarks of apoptosis," *Cardiovasc Res.* 2000 Feb;45(3):528-37.
- AR12 Saraste, A. *et al.* "Morphologic criteria and detection of apoptosis," *Herz.* 1999 May;24(3):189-95.
- AS12 Schon, E. *et al.*, "The role of dipeptidyl peptidase IV in human T lymphocyte activation. Inhibitors and antibodies against dipeptidyl peptidase IV suppress lymphocyte proliferation and immunoglobulin synthesis in vitro," *Eur. J. Immunol.* 1987 Dec;17(12):1821-6.
- AT12 Stein, R.L. *et al.* 1987, "Catalysis by human leukocyte elastase: Mechanistic insights into specificity requirements," *Biochem.* 26:1301-1305.
- AR13 Stein, R.L. *et al.* 1987, "Catalysis by human leukocyte elastase: Proton inventory as a mechanistic probe," *Biochem.* 26:1305-1314.
- AS13 Tanaka, T. *et al.*, 1993, "The costimulatory activity of the CD26 antigen requires dipeptidyl peptidase IV enzymatic activity," *Proc. Natl. Acad. Sci. USA.* 90: 4586-4590.
- AT13 Thiele, D.L. *et al.*, 1990, "Mechanism of L-leucyl-L-leucine methyl ester-mediated killing of cytotoxic lymphocytes: Dependence on a lysosomal thiol protease, dipeptidyl peptidase I, that is enriched in these cells," *Proc. Natl. Acad. Sci. USA* 87: 83-87.
- AR14 Valet *et al.*, "White cell and thrombocyte disorders. Standardized, self-learning flow cytometric list mode data classification with the CLASSIF1 program system," *Ann. NY Acad. Sci.* 1993 Mar 20;677:233-51.
- AS14 Watson, J., "Enzyme Kinetic Studies in Cell Population Using Fluorogenic Substrates and Flow Cytometric Techniques," *Cytometry*, 1(2), p. 143 (1980).
- AT14 Weiss. S.J. 1989, "Tissue destruction by neutrophils," *N. Eng. J. Med.* 320: 365-376.
- AR15 Whitlock, C.A., *et al.*, 1987. "Bone marrow stromal cell lines with lymphopoietic activity express high levels of a pre-B neoplasia-associated molecule," *Cell* 48: 1009-1021.
- AS15 Woessner, J.F. Jr., 1991, "Matrix metalloproteinases and their inhibitors in connective tissue remodeling," *FASEB J.* 5: 2145-2154.
- AT15 Wu, Q. *et al.*, 1991. "Aminopeptidase A activity of the murine B-lymphocyte differentiation antigen BP-1/6C3," *Proc. Natl. Acad. Sci, USA.* 88: 676-680.

The Examiner is requested to contact the undersigned immediately in the event that any cited document may be unavailable in order that a replacement copy can be provided.

Respectfully submitted,

Date: 11/2/2001


Jeffrey I. Auerbach
Registration No. 32,680